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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,820

12/30/2004

Henry Daniell

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

11/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,820

Applicant(s)

DANIELL, HENRY

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/22/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,28-30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23,28-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of group I (claims 1-23, 28-30 and 32-34) in the reply filed on 22 August 2007 is acknowledged.
2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
3. Fig 5A, Fig 7 and Fig 8 are objected to because letters within the black boxes cannot be made out.

Claim Objections

4. Claims 33-34 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.
5. Claim 21 is objected to because --said method-- should be inserted after "IGF-1" in line 1.
6. Claims 3 and 22-23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 fails to further limit claim 1 because it recites no structure that enables transforming a chloroplast but not other types of plastids.

Art Unit: 1638

Claims 22-23 fail to further limit because it does not recite any method step that makes the IGF-1 competent to produce an immunogenic response in a mammal or free of negative side effects; these are inherent to the method of claim 21.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-8, 10-15, 21-23, 28-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 7-8 lack antecedent basis for the limitation "said regulatory sequences" in line 1.

Claim 10 lacks antecedent basis for the limitation "said first and second flanking DNA sequences" in lines 2-3.

Claim 12 lacks antecedent basis for the limitation "said trnI and trnA" in line 1

Claim 12 is indefinite in its recitation of "to insert an IGF-1 or region of an inverted repeat region of a chloroplast genome". Words appear to be missing between "or" and "region", or between "of" and "an", or between "repeat" and "region", or possibly elsewhere in the claim.

Claim 13 is indefinite in its recitation of "wherein said DNA sequence coding for IGF-1 region of said plastid genome" as the DNA sequence is in the vector, not a plastid genome. It is unclear what Applicant means here.

Claim 21 lacks antecedent basis for the limitation "the IGF-1 product" in line 3.

Claim 28 lacks antecedent basis for the limitation "the transformation vector of claim 1".

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 7-13, 15-16, 19-23 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell (WO 01/72959).

Daniell teaches a plastid transformation vector comprising a first flanking sequence (trnI), a plastid promoter (Prn) operably linked to the selectable marker (aadA) operably linked as an operon to a codon optimized sequence encoding insulin-like growth factor (IFG-1) operably linked to a 3' UTR (TpsbA), and a second flanking sequence (trnA) (claims 18 and 37; pg 264, lines 13-26). A 5'UTR is positioned upstream of the promoter (claim 21; pg 264, lines 6-7)). Daniell et al also teaches a process comprising transforming a plant with the vectors (claim 27; pg 264, line 34, to pg 267, line 8), and teach producing progeny and seeds from the resulting plants (pg 267-, lines 12-18).

After transformation, the DNA sequence encoding IGF-1 would be in a single copy region of the plastid genome because no other region would have the DNA encoding IGF-1. Daniel also discloses SEQ ID NO:2, which is approximately 60% A+T, as the codon optimized sequence encoding IFG-1 (Figure 5 on pg 18/20). TrnA and trnI are from the inverted repeat region of the tobacco plastid genome and are used for homologous recombination; these

Art Unit: 1638

sequences are also highly conserved in plants (paragraph spanning pg 213-214), and because they encode tRNAs, this regions is transcriptionally active. Daniel

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-23, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 01/72959).

The claims are drawn to a plastid transformation vector comprising a first flanking sequence, a DNA encoding insulin-like growth factor (IFG-1), and a second flanking sequence, wherein the DNA is operably linked to the psbA 5' UTR. The claims are also drawn to an edible plant transformed with the vector.

The teachings of Daniell et al are discussed above.

Daniell does not disclose a plastid transformation vector encoding IFG-1, wherein it comprises the psbA 5' UTR or uses BADH as a selectable marker. Daniell does not disclose an edible plant transformed with the vector.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the psbA 5' UTR or use BADH as a selectable marker in the vector taught by Daniel.

One of ordinary skill in the art would have been motivated to use the psbA 5'UTR in the vector because its use increased protein expression levels in other cases (paragraph spanning pg 256-257) and because of Daniell's teachings to do so (pg 263, lines 5-11).

One of ordinary skill in the art would have been motivated to use BADH as a selectable marker because of Daniell's teachings that the selection agent glycine betaine is nontoxic (paragraph spanning pg 59-60), which would further allow the plant to be edible. Additionally, selection of one effective selectable marker over another is an obvious design choice.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to transform the vector taught by Daniel into an edible plant. One of ordinary skill in the art would have been motivated to use a tobacco that would be edible for mammals, such as that taught on pg 217, lines 27-31, because the lack of nicotine would reduce contaminants in protein purification. Additionally, the protein could then be fed to mammals without purification from the plant.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1638

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Anne Kubelik, Ph.D.
October 31, 2007

/Anne Kubelik/
Primary Examiner